

II. AMENDMENTS TO THE CLAIMS

1. (currently amended) A solid, oral, controlled release pharmaceutical dosage form which comprises an extrudate comprising a pharmaceutically active ingredient having a solubility in water of greater than 1gm in 250ml water at 25°C, said active ingredient dispersed in a matrix wherein the dosage form provides, as tested by the Ph. Eur. Basket method at 100 rpm 900 ml aqueous buffer (pH 6.5) containing 0.05% w/w Polysorbate 80 at 37°C, an essentially zero order rate of release of the pharmaceutically active ingredient over a period of 8 hours, the amount of pharmaceutically active ingredient released over eight hours being in the range of 15% to 45%, and when tested in a group of at least five healthy humans the median tmax, based on blood sampling at half hourly intervals, is in the range of from about 2.5 to about 6 hours, and the ratio of mean Cmax to the mean plasma level at 24 hours is in the range of about 1.5 to about 3.5, wherein said extrudate is directly incorporated into a capsule or tablet.
2. (original) A pharmaceutical dosage form according to claim 1, wherein the median tmax is in a range from 2.5 to 3.5 hours.
3. (previously presented) A pharmaceutical dosage form according to claim 1, which has a W₅₀ in the range from about 15 to about 35 hours when tested *in vivo* as set forth in claim 1.
4. (previously presented) A pharmaceutical dosage form according to claim 1, wherein the matrix comprises a mixture of an hydrophobic fusible material having a melting point of greater than 40°C and a hydrophilic, organic, polymeric fusible wicking agent.
5. (previously presented) A pharmaceutical dosage form according to claim 4, wherein the weight ratio of hydrophobic fusible material to hydrophilic, organic polymeric wicking agent in said mixture is in the range from about 8:1 to about 16:1.

6. (previously presented) A pharmaceutical dosage form according to claim 1, in which the pharmaceutically active ingredient is morphine, a pharmaceutically acceptable salt thereof or mixtures thereof.
7. (original) A pharmaceutical dosage form according to claim 5, which is suitable for once a day dosing.
8. (previously presented) A pharmaceutical dosage form according to claim 1, in the form of a tablet or a capsule containing multiparticulates.

9-10 (canceled)

11. (previously presented) A solid, oral controlled release pharmaceutical dosage form which comprises a pharmaceutically active ingredient having a solubility in water of greater than 1gm in 250ml water at 25 °C dispersed in a matrix, the dosage form being obtainable by a process comprising:

- (a) mechanically working in a high shear mixer a mixture of hydrophobic, fusible binder and a minor amount of an organic, fusible, polymeric material which in the finished dosage form is capable of functioning as a wicking agent at a speed and temperature at which the binder melts or softens and the mixture forms agglomerates;
- (b) extruding the agglomerates whereby the extrudate is obtained as extruded pieces or an elongate extrudate is formed into pieces;
- (c) continuing mechanically working the pieces in a high shear mixer; and
- (d) continuing mechanically working with additional binder material at a temperature and speed at which the additional binder melts or softens.

12. (previously presented) A pharmaceutical dosage form according to claim 1, which has a W_{50} in the range from about 20 to about 30 hours when tested *in vivo* as set forth in claim 1.
13. (previously presented) A pharmaceutical dosage form according to claim 1, in which the pharmaceutically active ingredient is morphine sulfate or morphine hydrochloride.
14. (previously presented) A pharmaceutical dosage form according to claim 4, wherein the median t_{max} is in the range from about 2.5 to about 3.5 hours.
15. (previously presented) A pharmaceutical dosage form according to claim 4, wherein the W_{50} is in a range from about 15 to about 35 hours.
16. (previously presented) A pharmaceutical dosage form according to claim 4, wherein the W_{50} is in a range from about 20 to about 30 hours.
17. (currently amended) A pharmaceutical dosage form according to claim 4, wherein the weight ratio of hydrophobic fusible material to hydrophilic organic polymeric wicking agent in said mixtures in the range from about 8:1 to about 16:1.
18. (previously presented) A pharmaceutical dosage form according to claim 4, wherein the pharmaceutically active ingredient is morphine, a pharmaceutically acceptable salt thereof or mixture thereof.
19. (previously presented) A pharmaceutical dosage form according to claim 4, wherein the pharmaceutically active ingredient is morphine sulfate or morphine hydrochloride.
20. (previously presented) A pharmaceutical dosage form according to claim 5, wherein the pharmaceutically active ingredient is morphine, a pharmaceutically acceptable salt thereof or mixture thereof.

21. (previously presented) A pharmaceutical dosage form according to claim 5, wherein the pharmaceutically active ingredient is morphine sulfate or morphine hydrochloride.
22. (previously presented) A pharmaceutical dosage form according to claim 1, which is suitable for once a day dosing.
23. (previously presented) A pharmaceutical dosage form according to claim 17, which is suitable for once a day dosing.
24. (previously presented) A pharmaceutical dosage form according to claim 4, in the form of a tablet or capsule containing multiparticulates.
25. (previously presented) A pharmaceutical dosage form according to claim 5, in the form of a tablet or capsule containing multiparticulates.